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PATENT

Attorney Docket 9577-25

CERTIFICATE OF MAILING

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November , 2004

Lisa Robinson

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Isa Odidi and Amina Odidi :
Serial No. 09/845,497 : Group Art Unit: 1616
Filed: May 1, 2001 : Examiner: Alton N. Pryor
For: Extended Release Pharmaceuticals

DECLARATION UNDER 37 C.F.R. 1.132

Box Fee Amendment
Commissioner for Patents
Washington, DC 20231

Isa Odidi and Amina Odidi declare that:

1. They are co-inventors of and are familiar with the present U.S. Patent Application Serial No. 09/845,497, and they are familiar with the Official Actions issued in the present application.
2. The polymers of the present application used as the encasement coating are soluble at a pH of above about 5.0.
3. In order to demonstrate that cellulose acetate is not soluble at a pH of above about 5.0, solubility studies have been conducted with respect to cellulose acetate and compared to anionic polymers of methacrylic acid and methacrylates (e.g. Eudragit L), which are shown in Schedule A.
4. These results show that cellulose acetate is not soluble above pH 5.0 and that anionic polymers of methacrylic acid and methacrylates (e.g. Eudragit L) are soluble above pH

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of 5.0. Therefore, Eudragit L and other anionic polymers of methacrylic acid and methacrylates are suitable polymers for the encasement coating of the present application and cellulose acetate is not a suitable polymer.

5. Isa Odidi and Amina Odidi further declare that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Isa Odidi

13 Nov 2004



AMINA ODIDI

13 Nov 2004

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SCHEDULE A

Cellulose Acetate Solubility

Solvent	Conc (g/mL)	Conc (g/100mL)	USP Descriptive Term
Phosphate buffer pH 5.0	0.0112	1.1237	Sparingly soluble
Phosphate buffer pH 6.5	0.0112	1.1237	Sparingly soluble
Phosphate buffer pH 7.5	0.0045	0.4495	Slightly soluble

Solubility of An Anionic Polymer of Methacrylic Acid and Methacrylates (Eudragit L)

Solvent	Conc (g/mL)	Conc (g/100mL)	USP Descriptive Term
Phosphate buffer pH 5.0	0.0374	3.7406	Soluble
Phosphate buffer pH 6.5	0.1000	9.9968	Freely soluble
Phosphate buffer pH 7.5	0.2720	27.2008	Freely soluble

Descriptive Terms

Parts of solvent required for 1 part of solute	Conc(g/mL)	USP descriptive term
< 1	more than 1	Very soluble
1 to 10	0.1 to 1	Freely soluble
10 to 30	0.0333 to 0.1	Soluble
30 to 100	0.01 to 0.0333	Sparingly soluble
100 to 1000	0.001 to 0.01	Slightly soluble
1000 to 10000	0.0001 to 0.001	Very slightly soluble
≥ 10000	Less than 0.0001	Practically insoluble